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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ODLAND, KATHRYN P	
ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 11/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/785,743	MURAYAMA ET AL.
	Examiner	Art Unit
	Kathryn Odland	3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,8,11-16,18,19,22,25-34 and 41-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *34 and 51* is/are allowed.

6)☒ Claim(s) *1,7,8,11-16,18,19,22,25-33 and 41-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/26/04*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated July 26, 2004. Claims 1, 7, 8, 11-16, 18, 19, 22, 25-34, and 41-51 are under consideration. The drawing submission is acknowledged.

Response to Arguments

1. Applicant's arguments filed July 26, 2004 regarding claims 1, 7, 8, 11, 18, 19, 22, 25, 26 and 27-33 have been fully considered but they are not persuasive.

Regarding claims 1 and 7, applicant has amended the claim to include positive recitation of treating an aneurysm in the body of the claim. However, applicant is reminded that functional language does not hold patentable weight in apparatus claims and the device of Strid is capable of being used in an aneurysm. The examiner agrees that the vascular environment is different than a tissue environment; however, the device of Strid is not restricted to the tissue environment and applicant's apparatus claim language does not recite structural limitations to define over that of Strid. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the apparatus from a prior apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Applicant argues, "Strid incorporate GHK-Cu2," which is irrelevant since the device of Strid is clearly capable of inducing controlled inflammation to induce controlled formation of scar tissue. The scope of this limitation is extraordinarily broad and most certainly there will be come inflammation and scar tissue and given the use of the

copolymers of poly-L-lactic acid and polyglycolic acid. The placement of the device in the body will most certainly cause an occlusion. Occlude is defined as to obstruct according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Moreover, there will necessarily be some scar tissue formation. Applicant also states, "Strid discloses that when poly-L-lactic acid and polyglycolic acid is used for artificial ligaments they hydrolyze so rapidly that collagenous scar tissue is not formed." However, this is not what the disclosure recites. Strid states, "Polymers of lactic and glycolic acid have been used for a long time as resorbable suture material. When this material is used for artificial ligaments the main problem is that they hydrolyze so rapidly that the body is not allowed enough time to replace them with its own tissue where collagen constitutes the main part." This by no means states that scar tissue is not formed. There will necessarily be some scar tissue formed and claim 1 further recites, "**without excessive formation of scar tissue**." That previously recited would further demonstrate that excessive scar tissue is not formed. Moreover, the scope of "excessive scar tissue" has not been established.

Regarding claim 18, although claim 18 is a method claim, claim 18 does not recite use in an aneurysm. Claim 18 merely recites, a method for creating an inflammatory response in a body cavity. Thus, the disclosed by Strid meets the claim limitations. The claim is extraordinarily broad. Placing the device of Strid in the body will occlude/obstruct the portion where it is placed. Further, there will be some "controlled" formation of scar tissue. The scope of "controlled" and "excessive scar

tissue formation" is not clear and the device of Strid can be considered to meet the claim limitations.

Regarding claim 25, see the above with respect to claims 1 and 7. Further, applicant argues, "Strid is totally silent as to any control of the degradation of the implant." However, the scope of "control" has not been established and there is no claim comparison to a metal coil. There will necessarily be degradation in the device of Strid and it can be considered to be in "control."

2. Applicant's arguments with respect to claim 34 and 51 have been fully considered and are persuasive. The rejection of claims 34 and 51 has been withdrawn.

3. Applicant's arguments with respect to claims 12-16 and 41-50 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 7, 11, 18, 22, 25-29, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Strid in US Patent No. 5,386,012.

Regarding claim 1, Strid discloses an apparatus for developing an inflammatory response in a body cavity capable of use in a vascular aneurysm with cellular manipulation having a separable implant, at least in part of at least one biocompatible and bioabsorbable polymeric material characterized by its

ability to induce controlled inflammation to induce controlled formation of scar tissue in a body cavity to substantially completely occlude the body cavity with out excessive formation of scar tissue, as recited in column 2 and claim 8. With respect to the phrase, "characterized by its ability to induce controlled inflammation to induce controlled formation of scar tissue in a body cavity to substantially completely occlude the body cavity with out excessive formation of scar tissue," applicant is reminded that functional language does not hold patentable weight in apparatus claims. Nonetheless, Strid discloses an implant with a copolymer of poly-L-lactic acid and polyglycolic acid, which would necessarily induce controlled inflammation to induce controlled formation of scar tissue in a body cavity to substantially completely occlude the body cavity with out excessive formation of scar tissue given the structure. Moreover, an endovascular placement device associated with the separable implant adapted to dispose the implant into the body cavity would be necessary and inherent.

Regarding claims 7 and 18, Strid discloses that as applied to claims 1 and 12, as well as, a biocompatible and bioabsorbable polymeric material that is at least one copolymer that is poly-L-lactic acid and polyglycolic acid, as recited in claim 8. Further, Strid discloses a method for creating an inflammatory response in a body cavity, as discussed above in the Response to Arguments section.

Regarding claim 11, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that promotes cellular manipulation, controlled inflammatory response and vascular healing. Applicant is again reminded that functional language does not hold patentable weight in apparatus claims, Nonetheless, that disclosed by Strid would necessarily achieve this limitation.

Regarding claim 22, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that does not elicit foreign body reaction, as recited throughout the specification.

Regarding claim 25, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymeric material that has a selected composition to provide a controlled degradation time to thereby control intravascular inflammatory reactions and degrading faster than by implanted metal coils and providing a stronger inflammatory reaction than metal coils. Again, applicant is reminded that functional language does not hold patentable weight in apparatus claims. Moreover, the scope of the comparison to implanted metal coils is unclear. Thus, given that disclosed by Strid when used to treat blood vessels as disclosed would necessarily provide a stronger inflammatory reaction than with a metal coil.

Regarding claims 26, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that regenerates tissue through the interaction of immunologic cells. Again, applicant is reminded that functional language does not hold patentable weight in apparatus claims. Nonetheless, given the composition disclosed by Strid, there necessarily would be a regeneration of tissue through the interaction of immunologic cells.

Regarding claims 27, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that stimulates cellular infiltration and proliferation in the process of degradation to accelerate fibrosis.
Again, applicant is reminded that functional language does not hold patentable weight in apparatus claims. Nonetheless, given the composition disclosed by Strid, there necessarily would stimulate cellular infiltration and proliferation in the process of degradation to accelerate fibrosis.

Regarding claims 28, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that would accelerates fibrosis within an aneurysm to more strongly anchor the implant than does metal coils. However, applicant has not positively recited in the claims that this invention is used in an aneurysm. Thus, given that disclosed by Strid when used to treat blood vessels as disclosed would necessarily accelerate fibrosis more than with a metal coil.

Regarding claims 29, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer is characterized by generating more connective tissue and a less unorganized clot than metal coils so that an aneurysm in which the implant is disposed is more resistant to a water hammer effect of pulsatile blood than when treated by metal coils. Again, the scope of the comparison with metal coils is unclear and there are no structural features provided to distinguish. Further, applicant has not positively recited an aneurysm. Thus, the scope of the claim is unclear.

Regarding claims 31, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that would necessarily restrict aneurysm recanalization by accelerated scar formation when used in treating blood vessels. Further, applicant has not positively recited an aneurysm. Thus, the scope of the claim is unclear.

Regarding claim 32, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that would necessarily induce organized connective tissue to fill an aneurysm and to retract the aneurysm over time due to maturation of collagen fibers to reduce aneurysm size and decrease aneurysm compression on brain parenchyma or cranial nerves when used in

treating blood vessels. Again, functional language does not hold patentable weight in apparatus claims.

Regarding claim 33, Strid discloses that as applied to claim 1, as well as, a biocompatible and bioabsorbable polymer that is less thrombogenic than metal coils and would accelerate aneurysm healing with less thrombogenicity. Again, the scope of the comparison with metal coils is unclear.

6. Claims 12-16 and 41-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Conston et al. in US Patent No. 5,456,693.

Regarding claim 12, Conston et al. discloses a method of creating an inflammatory response in a vascular aneurysm (column 1, lines 18-22) via causing substantially complete occlusion, of the body cavity by inducing the *controlled formation of scar tissue in the body cavity without excessive formation of scar tissue* by providing a separable implant having at least one biocompatible and bioabsorbable polymeric material (column 1, lines 8-10) characterized by its ability to induce *controlled inflammation*; and disposing the implant in the body cavity, as recited throughout the specification. See the corresponding rejection for claim 1. Further, where the implant is placed is considered the cavity and given that it occupies the space it can be considered to occlude the space that it takes up. The scope of "controlled formation of scar tissue in the body cavity

without excessive formation of scar tissue" and "controlled inflammation is unclear." However, claim 3 and column 4 would yield that recited in the claim.

Regarding claim 13, Conston et al. discloses that as applied to claim 12, as well as, an implant with a noncollagenous protein, as recited in column 4, lines 50-60.

Regarding claim 14, Conston et al. discloses that as applied to claim 12, as well as, an implant that further is at least in part of a growth factor, such a collagen.

Regarding claim 16, Conston et al. discloses that as applied to claim 14, as well as, a growth factor that is a basic fibroblast growth factor, such a collagen.

Regarding claim 41, Conston et al. discloses that as applied to claim 12, as well as, causing substantially complete occlusion via degrading the biocompatible and bioabsorbable polymeric material faster than by implanted metal coils and providing a stronger inflammatory reaction than metal coils. Given that disclosed by Conston et al. a stronger inflammatory reaction than metal coils would necessarily occur given the structure and composition of the plug.

Regarding claim 42, Conston et al. disclose that as applied to claim 12. Further the scope of "controlled degradation time" has not been established. Thus, that

disclosed by Conston et al. can be considered within the scope of controlled degradation.

Regarding claim 43, Conston et al. disclose that as applied to claim 12, as well as regenerating tissue via interaction of immunologic cell by the biocompatible and bioabsorbable polymeric material, as recited throughout with emphasis on column 1, column 4 and claim 3.

Regarding claims 44 and 45, Conston et al. disclose that as applied to claim 12, as well as causing substantially complete occlusion via stimulating cellular infiltration and proliferation in the degradation process to accelerate fibrosis and more strongly anchor the implant than accomplished by metal coils via the biocompatible and bioabsorbable polymeric material, as recited throughout with emphasis on column 1, column 4 and claim 3.

Regarding claim 46-50, Conston et al. disclose that as applied to claim 12. Further, given the structure disclosed by Conston et al. restricting aneurysm recanalization by accelerating scar formation inducing organized connective tissue and accelerating healing with less thrombogenicity than with metal coils would necessarily occur.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 8, 19, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strid in US Patent No. 5,386,012.

Regarding claims 8 and 19, Strid discloses that as applied to claims 1 and 12. However, Strid does not recite a biocompatible and bioabsorbable protein that is at least one protein selected from the group consisting of fibrinogen, fibronectin, vitronectin, and laminin. On the other hand, it would be obvious to one with ordinary skill in the art to include a protein selected from the group consisting of fibrinogen, fibronectin, vitronectin, and laminin, depending on the implantation site, for they are extraordinarily well known to one with ordinary skill in the art.

Regarding claims 30, Strid discloses that as applied to claims 1. However, Strid does not explicitly recite an implant that is a coil. On the other hand, Strid discloses an artificial implant where a coil would fall within the scope of an artificial implant. Thus, it would be obvious to one with ordinary skill in the art to have the implant be a coil.

7. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Conston et al. in US Patent No. 5,456,693.

Regarding claim 15, Conston et al. disclose that as applied to claim 12. However, an implant with a vascular endothelial growth factor has not been explicitly recited. On the other hand, an endothelial growth factor would be obvious if not inherent to one with ordinary skill in the art. Further, the current application specification does not demonstrate the criticality for that particular type of growth factor over any other types. Thus, all growth factors can be considered equivalents.

Allowable Subject Matter

8. Claim 34 and 51 allowed.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KO

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